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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,958	01/30/2002	Todd K. Rosengart	3183-001-01	7923

7590

12/29/2003

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EXAMINER

ROBERT, EDUARDO C.

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/060,958

Applicant(s)

ROSENGART, TODD K.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 1-65 and 97-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-77 and 105 is/are rejected.
- 7) ☒ Claim(s) 78-96 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 April 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6-8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention III (claims 66-96 and 105) in Paper No. 10, is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner to search all the inventions. This is not found persuasive because contrary to applicant's opinion searching 5 different inventions, which applicant has not denied, would be burdensome for the examiner and it is clearly shown by their different classification and/or search in the restriction requirement mailed on October 2, 2003 (Paper no. 9). Moreover, the restriction requirement complies with the two-way or one-way distinctions requirement (see restriction requirement, paper no. 9).

Claims 1-65 and 97-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to because Figure 7 appears to contain 2 separate figures, and thus each figure should be labeled separately, e.g. Figure 7.1, Figure 7.2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Applicant is required to submit a proposed drawing correction in response to this Office Action. Any proposal by the applicant for amendment of the drawings to cure defects must consist of two parts:

- a) A separate letter to the Draftsman in accordance with MPEP § 608.02(r); and
- b) A print or pen-and-ink sketch showing changes in red ink in accordance with MPEP § 608.02(v).

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch with proposed corrections shown in red ink is required in response to this Office Action, and may not be deferred.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There exists an inconsistency between the language of claim 67 and that of the claim 74 dependent thereon, thus making the scope of the claims unclear. In claim 67 applicant recites a “graft delivery system” with the coupler being only functionally recited, i.e. “said third elongated instrument delivers a coupler to a severed end ...”, thus indicating that the claims are directed to the subcombination, “graft delivery system”. However, in claim 74, lines 1-2, applicant positively recites the coupler as part of the invention, i.e. “said coupler comprises a compressible ring ...”, thus indicating that the combination, graft delivery system and coupler, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is

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consistent with this intent. For examination purposes the claims will be considered as being drawn to the subcombination, graft delivery system. Claims 75 and 76 depend from claim 74 and 77 have problems similar to the one of claim 74. It is noted that, as stated above, the claims will be considered as being drawn to the subcombination graft delivery system.

Claim Objections

Claims 66-68 are objected to because of the following informalities:

In claim 66, line 1, "using" should be changed to -- for using in -- in order to make the claim more clear. It will be considered as such for examination purposes.

In claim 67, line 4, "delivers" should be changed to -- is for delivering -- in order to make the claim more clear. It will be considered as such for examination purposes.

In claim 68, line 2, "delivers" should be changed to -- is for delivering -- in order to make the claim more clear. It will be considered as such for examination purposes.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 70, 71, and 76 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 70, lines 1-2, applicant positively recites part of a human, i.e. "said mammary guide device protrudes outside of said patient's thoracic region". In claim 71, lines 1-2, applicant positively recites part of a human, i.e. "said coronary catheter protrudes

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outside of said patient's thoracic region". In claim 76, lines 1-2, applicant positively recites part of a human, i.e. "said ring is compressed inside said conical-shaped device at said exterior of said patient's thoracic region". Thus claims 70, 71, and 76 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 66, 67, 71-73, and 77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44, 45, 49-51, and 56 of copending Application No. 10/175,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the copending application claims lies in the fact that the copending

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application claims include more elements and are thus much specific. Thus the invention of the copending application claims are in effect a “species” of the “generic” invention of the application claims. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the copending application claims, they are not patentably distinct from the copending application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66-71, 74-77 and 105, as understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. (U.S. Patent 6,508,252).

Berg et al. discloses a system comprising an elongated instrument comprising a mammary catheter 160 and a mammary guide 210 (see col. 19, lines 58-67). The system further comprises another elongated instrument comprising a coronary catheter and guide wire (see for example Figures 9, 29-32). The system also has a retrieving device, e.g. 250. The system further

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has another elongated instrument, i.e. mammary catheter 330, for delivering a coupler or connector, e.g. 60. The catheter 330 delivers the coupler to a severed end of the mammary artery (see for example Figure 45) and it has at least a balloon 332. The mammary guide and coronary catheter are capable of protruding outside the patient's thoracic region. The coupler comprises a compressible ring (see col. 20, lines 6-8). The ring is compressed inside a conical shaped device 322 (see for example Figure 45). The system also has a sheath part over the coupler 60 (see Figure 45).

Claims 66 and 73, as understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Grudem et al. (U.S. Patent 6,511,491).

Grudem et al. disclose a system comprising an elongated instrument comprising a mammary catheter 17a and a mammary guide 160 (see Figure 13). The system further comprises another elongated instrument comprising a coronary catheter, e.g. 152, and guide wire, e.g. 150 (see for example Figure 9). The system also has a retrieving device or catheter 182 that has a hollow cone device 180 (see Figure 13).

Allowable Subject Matter

Claims 78-96 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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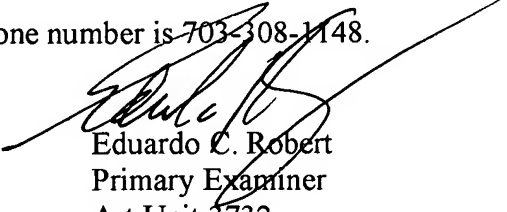
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.